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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,998	04/12/2002	David N. Armstrong	10148-1020	6172
24504	7590	12/13/2004	EXAMINER	
THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP 100 GALLERIA PARKWAY, NW STE 1750 ATLANTA, GA 30339-5948			MENDOZA, MICHAEL G	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/042,998	ARMSTRONG, DAVID N.
	Examiner	Art Unit
	Michael G. Mendoza	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 August 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 26-35 and 55-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 26-35 and 55-77 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 26-35 have been considered but are moot in view of the new ground(s) of rejection.

Specification

2. The amendment filed 30 August 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "The pawl 72 moves with the firing handle 21 to engage the ratchet 74 of the central rod to pull the inner cylinder 12 through the outer cylinder 11 and eject one of the rubber bands from the surface of the inner cylinder", and "the central rod 14 can be rotated about its longitudinal axis to disengage its ratchet teeth from the pawl 72 and spring 76, thus freeing the central rod and the inner cylinder for longitudinal movement". The pawl 72 is not found in the original disclosure

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 64 and 75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner was unable to find in the specification wherein the handle is oriented on the flange to be at twelve o'clock when the openings in the cylinder are oriented in the nine o'clock, one o'clock and five o'clock positions.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 26-35, 55-63, 65-74, 76, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson Jr. et al. ⁵ 6,788,715 in view of Bayer 6,126,594 in further view of Bidoia 5,203,863.

7. Watson teaches a system for ligation of internal hemorrhoids comprising a ligator device configured to store multiple bands on a cylinder and further configured to release a single rubber band at a time from the cylinder. No anoscope or loading cone is disclosed by Watson. Bayer teaches an anoscope with a hollow cylinder with multiple apertures formed about the hollow cylinder at positions about the hollow cylinder for simultaneously exposing hemorrhoids in the anal canal (col. 1, lines 63-64; see figure). To perform a hemorrhoid surgery it is well known in the art to use an anoscope to allow the ligation tool to enter the anus. Bayer describes instruments can be disposed

through the anoscope to access any number of hemorrhoids (col. 1, lines 56-67). At the time of the invention it would have been obvious to one having ordinary skill in the art to combine the Watson device with the anoscope of Bayer because Bayer teaches that hemorrhoid surgery is performed by using a ligating instrument and an anoscope. The combined device does not disclose a reloading mechanism for placing rubber bands onto the Watson device in the event additional bands are needed, or if the surgery is repeated. Bidoia discloses a loading mechanism that allow multiple rubber bands to be placed on the inner cylinder of the Watson device. At the time of the invention it would have been obvious to one having ordinary skill in the art to use the Bidoia loading cone to load the Watson ligator for allowing bands to be replace onto the device.

8. Regarding claims 27, 56, 58, 59, 65, 67, 69, 70, and 76 the Bayer anoscope discloses a plurality of apertures. Bayer fails to teach 3 apertures that extend laterally in a longitudinal direction approximately half-way along a length of the anoscope, and each aperture having a width approximately equivalent to one-sixth of a circumference of the anoscope. However, it would have been obvious to one having ordinary skill in the art to make the anoscope of Bayer as recited because the dimensions of the anoscope are a mere design choice. Furthermore, the Applicant has not disclosed that the specific dimensions solves any stated problems or is for any particular purpose and it appear that the invention would perform equally well with the dimensions taught by Bayer.

9. Regarding claim 28 and 29, the Watson ligator anticipated all the limitation of these claims. The examiner has attached a sheet labeling all of the corresponding

parts. Inner cylinder is element 1, outer cylinder 2, central rod 3, outer rod 4, and handle 5.

10. Regarding claim 30, the Watson device is structurally capable of having the inner cylinder removed to allow the reloading of multiple rubber bands.

11. Regarding claim 31, as disclosed the Watson device is structurally capable of having its inner cylinder removed and a new preloaded one place in the old inner cylinder's place.

12. Regarding claim 32, the disposable cylinder is labeled on the attached figure as element 6. The shoulder is the element that pushes the band off of the cylinder (7).

13. Regarding claim 35, the modified loading cone is configured with a tapered front section (35) and shouldered recess (31).

14. Regarding claims 55, 63, 66, and 74, the anoscope of Bayer comprises: the cylinder defining three lateral apertures, the apertures being spaced apart about the cylinder to be positionable at the three o'clock, seven o'clock and eleven o'clock positions about the cylinder (see figure).

15. Regarding claims 57 and 68, Bayer fails to specifically teach wherein the cylinder is tapered. However, it is well known in the art of anoscopy to use a tapered design to aid insertion into the anus. Therefore it would have been obvious to one having ordinary skill in the art to taper the cylinder of Bayer to make the insertion of the anoscope easier.

16. Regarding claims 60, 61, 71, 72, and 77, the anoscope of Bayer comprises: a flange extending radially from the proximal end of the cylinder and a handle extending from the flange.

17. Regarding claims 62 and 73, Bayer discloses the an optic fiber or light can be part of the anoscope (col. 3, lines 20-27).

18. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined Watson device as applied to claim 29 and in view of Lindquist 3997085. The Watson device uses a very simple handle to affect the necessary force on the inner cylinder to discharge the ligation bands. There are a myriad of different types of handles that are well-known in the art that could be substituted for the Watson handle. A spring-clip handle is disclosed by Lindquist. This type of handle automatically applies force in the reverse direction, which provides resistance to the trigger. This would be beneficial to use on the Watson device because this handle would help prevent misfiring. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute the Watson handle with the Lindquist handle because the Lindquist handle would be more effective in preventing accidental actuation of the handle than the pull cord design of Watson.

19. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over combined Watson device as applied to claim 29 and in view of Aranyi 5483952. As mentioned above, Watson discloses only a rudimentary handle to actuate the ligation bands. Spring-based ratchet handles are well known in art. A dual spring mechanism wherein the central rod also functions as a ratchet is taught by Aranyi '952. This design

is advantageous since it affords the user the benefit of using a ratchet and keeps the number of moving parts to a minimum. The Aranyi handle has a first spring which is used to withdraw the serrated central rod and a second spring used to stabilize and prevent forward slippage of the central rod. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute the Aranyi handle into the combined Watson device to afford the Watson device ratcheting functionality.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

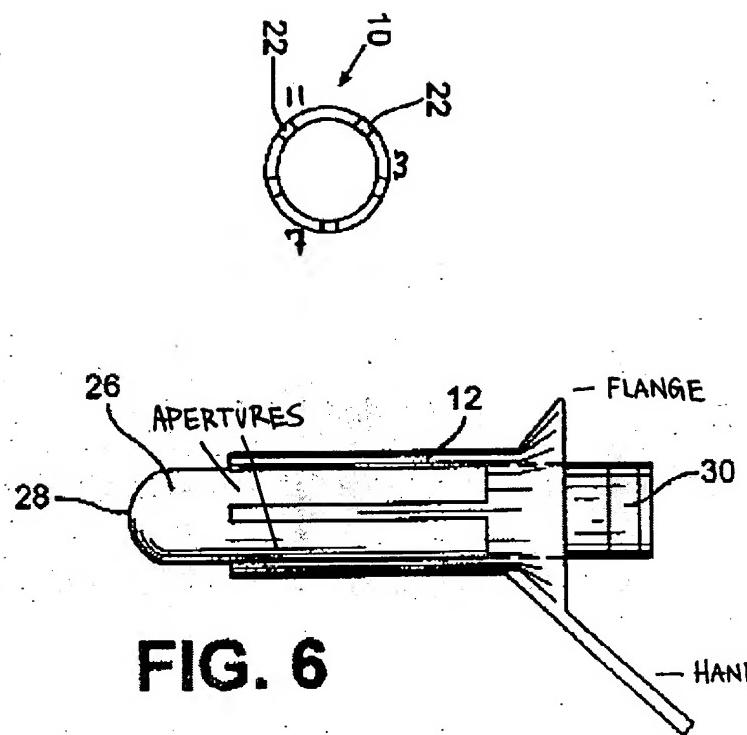
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Dawson can be reached on (571) 272-4694. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MM

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GLENN K. DAWSON
PRIMARY EXAMINER

**FIG. 6**